

Notice of Allowability

Application No.

09/634,960

Examiner

Jehanne E Souaya

Applicant(s)

KARLSEN, FRANK

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1634

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is responsive to the proposed amendment filed January 14, 2003.
2. ☒ The allowed claim(s) is/are 1-3, 6, 8, 13, 14, 16-19 and 26-39.
3. ☐ The drawings filed on _____ are accepted by the Examiner.
4. ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some* c) ☐ None of the:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).
- * Certified copies not received: _____.
5. ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
(a) ☐ The translation of the foreign language provisional application has been received.
6. ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application. **THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.**

7. ☐ A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.
8. ☐ CORRECTED DRAWINGS must be submitted.
(a) ☐ including changes required by the Notice of Draftsperson's Patent Drawing Review (PTO-948) attached
1) ☐ hereto or 2) ☐ to Paper No. _____.
(b) ☐ including changes required by the proposed drawing correction filed _____, which has been approved by the Examiner.
(c) ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No. _____.

Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the top margin (not the back) of each sheet. The drawings should be filed as a separate paper with a transmittal letter addressed to the Official Draftsperson.

9. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

Attachment(s)

- | | |
|--|---|
| 1 <input type="checkbox"/> Notice of References Cited (PTO-892) | 2 <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3 <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 4 <input checked="" type="checkbox"/> Interview Summary (PTO-413), Paper No. _____ |
| 5 <input type="checkbox"/> Information Disclosure Statements (PTO-1449), Paper No. _____ | 6 <input checked="" type="checkbox"/> Examiner's Amendment/Comment |
| 7 <input type="checkbox"/> Examiner's Comment Regarding Requirement for Deposit of Biological Material | 8 <input checked="" type="checkbox"/> Examiner's Statement of Reasons for Allowance |
| | 9 <input type="checkbox"/> Other |

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EXAMINER'S AMENDMENT

1. An examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it MUST be submitted no later than the payment of the issue fee.

Authorization for this examiner's amendment was given in a telephone interview with Christopher Corbett on February 27, 2002.

2. The application has been amended as follows:

In claims 19, 34, and 39, delete the recitation of "one of" in line 1. Also, delete the recitation of "and" and replace it with the word --or--.

In claim 28, line 7, insert the word --for-- in between the recitation of 'E.coli' and 'forming'.

REASONS FOR ALLOWANCE

3. The following is an examiner's statement of reasons for allowance:

The claims are drawn to oligonucleotide primers having up to 40 bases and comprising SEQ ID NO 1-3 or 14-16. The claims are also drawn to kits for detecting E. Coli, the kits comprising a primer pair having a first primer comprising SEQ ID NO 1, SEQ ID NO 2, or SEQ ID NO 3, and the second primer comprising SEQ ID NO 14, SEQ ID NO 15, or SEQ ID NO 16, respectively. The claims are drawn to methods for detecting E. Coli in a liquid or liquefied

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sample using a primer set that is specific for E. Coli, wherein the primer set comprises SEQ ID NO 1 and SEQ ID NO 14, or SEQ ID NO 2 and SEQ ID NO 15 or SEQ ID NO 3 and SEQ ID NO 16. The claims are further drawn to a method for detecting E. Coli, but not *Shigella boydii*, *Shigella flexneri*, *Salmonella typhi*, *Salmonella enterica*, *Salmonella arizonae*, *Enterobacter cloacae*, *Enterobacter aeromonas*, *Enterococcus faecalis*, *Enterococcus faecium*, *Streptococcus pyogenes*, *Pseudomonas* species, *Aeromonas hydrophila*, *Acinetobacter* species, *Klebsiella pneumoniae*, *Listeria monocytogenes*, *Neisseria meningitidis*, *Campylobacter jejuni*, *Campylobacter coli*, *Erwinia* species, and *Citrobacter freundii* in a liquid or liquefied sample comprising recovering bacteria from a liquid or liquefied sample, lysing the bacteria to provide a DNA sample, selecting a target gene of E. Coli and selecting an E. Coli specific target DNA sequence, incubating the DNA under amplification conditions with a primer pair specific for E. Coli but not *Shigella boydii*, *Shigella flexneri*, *Salmonella typhi*, *Salmonella enterica*, *Salmonella arizonae*, *Enterobacter cloacae*, *Enterobacter aeromonas*, *Enterococcus faecalis*, *Enterococcus faecium*, *Streptococcus pyogenes*, *Pseudomonas* species, *Aeromonas hydrophila*, *Acinetobacter* species, *Klebsiella pneumoniae*, *Listeria monocytogenes*, *Neisseria meningitidis*, *Campylobacter jejuni*, *Campylobacter coli*, *Erwinia* species, and *Citrobacter freundii* for amplifying the target DNA sequence, and detecting the presence of amplified DNA as a specific indication of the presence of E. Coli carrying the selected E. Coli specific target DNA sequence, wherein the target gene is the *lamB* gene of E. Coli.

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The closest prior art is that of Atlas et al (US Patent 5,298,392) which teaches methods and kits for detection of water borne pathogens in water samples. Further, Clement (Cell, vol 27, pp 507-514; 1981) teaches the sequence of the E. Coli *lamB* gene. Although Atlas specifically teaches primers, and methods of using primers for the *lamB* gene of E. Coli, the claims are allowable over the prior art of Atlas et al, alone or in combination with the teachings of Clement, because Atlas et al do not teach or fairly suggest primers with the sequences of the instantly claimed primers (a primer having up to 40 nucleotides and comprising SEQ ID NO 1, SEQ ID NO 2, SEQ ID NO 3, SEQ ID NO 14, SEQ ID NO 15, or SEQ ID NO 16), do not teach primer pairs of the instantly claimed invention (primer pairs comprising a first primer comprising SEQ ID NO 1, and a second primer comprising SEQ ID NO 14, or a first primer comprising SEQ ID NO 2 and a second primer comprising SEQ ID NO 15, or a first primer comprising SEQ ID NO 3 and a second primer comprising SEQ ID NO 16) , and further do not teach or suggest to use the same region of the *lamB* gene of E. Coli for PCR or hybridization based detection purposes. Further, the primers used in the method of Atlas et al, not only detected E. Coli, but *Salmonella typhimurium* and *Shigella* species as well. Even at higher primer annealing temperatures, *Shigella* species were still detected in the method of Atlas et al. Therefore, Atlas et al also do not teach or suggest a method for detecting E. Coli but not *Shigella boydii*, *Shigella flexneri*, *Salmonella typhi*, *Salmonella enterica*, *Salmonella arizonae*, *Enterobacter cloacae*, *Enterobacter aeromonas*, *Enterococcus faecalis*, *Enterococcus faecium*, *Streptococcus pyogenes*, *Pseudomonas* species, *Aeromonas hydrophila*, *Acinetobacter* species, *Klebsiella pneumoniae*,

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Listeria monocytogenes, *Neisseria meningitidis*, *Campylobacter jejuni*, *Campylobacter coli*, *Erwinia* species, and *Citrobacter freundii*, using primers for the *lamB* gene. The primers and primer pairs of the instantly claimed invention, as well as kits comprising such, and methods of using such are also unobvious over the teachings of Atlas et al because neither Atlas et al, nor the prior art in general, teach an alignment of the *lamB* gene from different bacterial species, such that the skilled artisan would be able to determine nucleic acid sequence differences that could be used to differentiate between E coli and other closely related bacterial species, such as Salmonella or Shigella species, and arrive at the primers or primer pairs of the instantly claimed invention.

Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

4. Applicant's arguments with regard to the priority of the instantly pending claims are acknowledged but will not be addressed because the issue is moot as the arguments have no bearing on the allowability of the claims since there is no intervening art between the priority date and the filing date of the instant application.

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5. Any inquiry concerning this communication or earlier communications from the examiner should be directed to examiner Jehanne Souaya whose telephone number is (703)308-6565. The examiner can normally be reached Monday-Friday from 9:00 AM to 6:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Jones, can be reached on (703) 308-1152. The fax phone number for this Group is (703) 305-3014.

Any inquiry of a general nature should be directed to the Group receptionist whose telephone number is (703) 308-0196.



Jehanne Souaya
Patent examiner
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3/3/03